

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION IX

75 Hawthorne Street San Francisco, CA 94105-3901

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

7016 1370 0000 2234 5373

Joe Drake, President Decon7 Systems LLC 8541 E. Anderson Dr. #106 Scottsdale, AZ 85225

Re:

STOP SALE, USE, OR REMOVAL ORDER

Decon7 Systems LLC

Dear Mr. Drake:

Enclosed is a Stop Sale, Use, or Removal Order ("Order") issued by the U.S. Environmental Protection Agency Region 9 (EPA) to Decon7 Systems LLC., concerning all pesticide products bearing the name and registration number, Decon7 Part 1 / EPA Reg # 74436-1-89833 and Decon7 Part 2 / EPA Reg # 74436-2-89833 and any alternate brand names. The order is effective immediately upon receipt.

Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136k(a), authorizes the EPA to issue an order prohibiting the sale, use, or removal of any pesticide by any person who owns, controls, or has custody of such pesticide whenever there is reason to believe on the basis of inspection that such pesticide is in violation of any provision of FIFRA or that such pesticide has been or is intended to be distributed or sold in violation of FIFRA. As explained further in the enclosed Order, Decon7 Systems LLC has been and is producing, distributing, or selling, misbranded and unregistered pesticide products in violation of FIFRA.

EPA developed an information sheet entitled "U.S. EPA Small Business Resource Information Sheet" to help small businesses understand federal and state environmental laws and rights under the Small Business Regulatory Enforcement Fairness Act. The information sheet is enclosed.

If you have any questions about this matter, please contact Scott McWhorter, Enforcement Case Officer, at 415-972-3584. For any legal matters concerning this matter, please contact Margaret Alkon, Assistant Regional Counsel, at 415-972-3890.

Sincerely,

Elizabeth Berg

Acting Assistant Director

Water and Pesticides Branch, Enforcement Division U.S. Environmental Protection Agency, Region IX

Enclosures

7016 1370 0000 2234 5380

CC: LRR Agent Service of Arizona, Attn: Decon7 Systems LLC, 1 S Church Ave, STE 700 TUCSON, AZ 85260

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION IX 75 HAWTHORNE STREET SAN FRANCISCO, CA 94105

In the matter of:)	ORDER
)	SECTION 13(a)
)	
Decon7 Systems LLC)	FEDERAL INSECTICIDE, FUNGICIDE
)	AND RODENTICIDE ACT
)	
Respondent.)	Docket No. FIFRA-09-2018-4005

I. AUTHORITIES

- 1. The United States Environmental Protection Agency ("EPA") is authorized under Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136k(a), to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is a reason to believe that, *inter alia*, the pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- This authority has been delegated from the EPA Administrator to the Assistant Director of the Water & Pesticides Branch, Enforcement Division, EPA, Region IX.
- Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 4. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a "pesticide" in part, as any "substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." See also 40 C.F.R. § 152.15.

- 6. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "labeling" in part, as "all labels and all other written, printed, or graphic matter
 - (A) accompanying the pesticide or device at any time; or
 - (B) to which reference is made on the label or in literature accompanying the pesticide..." and defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers."
 - Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q), states that "a pesticide is misbranded if (A) its labeling bears any statement, design, or graphic representation relative
 thereto or to its ingredients which is false or misleading in any particular;
 - (E) Any word, statement, or other information required by or under the authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared to other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; ..."
 - 8. Pursuant to the authority in section 25(a) of FIFRA, 7 U.S.C. § 136w(a), the Administrator promulgated the labeling requirements for pesticides found at 40 CFR Part 156, and 40 C.F.R. § 156.10(a)(5) provides examples of false and misleading statements or representations in the labeling which constitute misbranding. They include but are not limited to:
 - (a) A false or misleading statement concerning the effectiveness of the product as a pesticide or device (40 C.F.R. § 156.10(a)(5)(ii));
 - (b) A false or misleading comparison with other pesticides or devices (40 C.F.R. § 156.10(a)(5)(iv));
 - (c) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government (40 C.F.R. § 156.10(a)(5)(v));
 - (d) A true statement used in such a way as to give a false or misleading impression to the purchaser (40 C.F.R. § 156.10(a)(5)(vii));
 - (e) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed" (40 C.F.R. § 156.10(a)(5)(ix)); and
 - (f) Non-numerical and/or comparative statements on the safety of the product, including but not limited to: (A) "Contains all natural ingredients"; (B) "Among the least toxic chemicals known" (C) "Pollution approved" (40 C.F.R. § 156.10(a)(5)(x)).

- 9. Section 3(a) of FIFRA, 7 U.S.C. § 136a, provides that "no person in any State may distribute or sell to any person any pesticide that is not registered under this Act." See also 40 C.F.R. 152.15, which also provides that no person may distribute or sell any pesticide that is not registered under the Act, with certain exceptions not applicable here.
- 10. Section 3(c)(1)(C) of FIFRA, 7 U.S.C. § 136a, provides that the statement that each applicant for registration of a pesticide must file a statement includes "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use."
- 11. 40 C.F.R. § 152.132 provides for "supplemental distribution" the term for when the registrant may distribute or sell his registered product under another person's name and address, and such distributor is considered an agent of the registrant for all intents and purposes under the Act. Supplemental distribution is permitted upon notification to EPA if all the following conditions are met:
 - (a) The registrant has submitted to the Agency for each distributor product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor's company number, the additional brand name(s) to be used, and the registration number of the registered product. (40 C.F.R. § 152.132(a))
 - (b) The distributor product is produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with §152.30) who produces, packages, and labels the registered product. (40 C.F.R. § 152.132(b))
 - (c) The distributor product is not repackaged (remains in the producer's unopened container). (40 C.F.R. § 152.132(c))
 - (d) The label of the distributor product is the same as that of the registered product, except that: (1) The product name of the distributor product may be different (but may not be misleading); (2) The name and address of the distributor may appear instead of that of the registrant; (3) The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the Agency upon request); (4) The establishment number must be that of the final establishment at which the product was produced; and (5) Specific claims may be deleted, provided that no other changes are necessary. (40 C.F.R. § 152.132(d))
 - (e) Voluntary cancellation of a product applies to the registered product and all distributor products distributed or sold under that registration number. The registrant is responsible for ensuring that distributors under his cancelled registration are notified and comply with the terms of the cancellation. (40 C.F.R. § 152.132(e)).

- 12. Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), states, "it shall be unlawful for any person in any State to distribute or sell to any person... any registered pesticide if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration" under section 3 of FIFRA.
 - 13. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states, "it shall be unlawful for any person in any State to distribute or sell to any person . . . any pesticide that is not registered . . . or whose registration has been suspended or cancelled."
 - Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states, "it shall be unlawful for any person in any State to distribute or sell to any person . . . any pesticide which is adulterated or misbranded."
 - 15. Section 12(a)(2)(S) of FIFRA, 7 U.S.C. § 136j(a)(2)(S), states, "it shall be unlawful to violate any regulation issued under FIFRA section 3(a) or section 19."
 - Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(1), states that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.

II. BACKGROUND

- 17. This Order refers to Decon7 Systems, LLC as "Decon7," or the "Respondent."
 - Decon7 is located and incorporated in the state of Arizona. Decon7 is a "person" as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).
- Respondent distributes and sells pesticides to customers located throughout the United States, including Arizona, California, Connecticut, Ohio, Minnesota and Texas.
- Respondent has been a supplemental distributor for EFT Holdings, Inc. ("EFT Holdings"). EFT Holdings is the registrant of EasyDecon Penetrator 200-5000, a pesticide which has been assigned the EPA Registration Number (EPA Reg. No.) 74436-1, and EasyDecon 0213 Fortifier, a pesticide which has been assigned EPA. Reg. No. 74436-2.
- 21. Respondent has been a supplemental distributor of EasyDecon Penetrator 200-5000 under distributor product names that include "Decon Seven Part 1" and "D7 Part 1" and with the EPA Reg. No. 74436-1-89833 ("Decon Seven Part 1") and EasyDecon 0213 Fortifier under distributor product names that include "Decon7 Part 2" and "D7 Part #2" and with the EPA Reg. No. 74436-2-89833 ("Decon Seven Part 2").1

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¹ It is a common practice for a registered product to have alternate brand names. In accordance with 40 CFR § 152.46 and Pesticide Registration (PR) Notice 98-10, alternate brand names are submitted to the EPA for approval using the notification procedures outlined in that PR Notice.

- 22. Decon Seven Part 1 and Decon Seven Part 2 are mixed together for use.
 - (a). The active ingredient of Decon Seven Part 1 is n-Alkyl (C12-C16)-N, N-dimethyl-N-benzylammonium chloride (3.2%).
 - (b). The active ingredient of Decon Seven Part 2 is Hydrogen Peroxide (7.98%).
 - (c). Decon Seven Part 1 and Decon Seven Part 2 each have the signal word "Danger" as is required of a Toxicity Category Class I Pesticide, the most toxic pesticide classification under EPA's labeling regulations at 40 C.F.R. §156.62.
- 23. Effective August 15, 2017, EPA conditionally approved the registrations for the products D7 Part 1 with the EPA Reg. No. 89833-3 ("D7 Part 1") and D7 Part 2 with the EPA Reg. No. 89833-4 ("D7 Part 2") (together, these are the "New D7 Products"). Respondent is the registrant of the New D7 Products.
- 24. The New D7 Products are also mixed together for use.
 - (a). The active ingredient of D7 Part 1 is n-Alkyl (C12-C16)-N, N-dimethyl-N-benzylammonium chloride (3.2%).
 - (b). The active ingredient of D7 Part 2 is Hydrogen Peroxide (7.98%).
 - (c). D7 Part 1 and D7 Part 2 each have the signal word "Danger" as is required of a Toxicity Category Class I Pesticide, the most toxic pesticide classification under EPA's labeling regulations at 40 C.F.R. §156.62.
- 25. In an email dated November 30, 2015, Respondent sent to EFT Holdings' agent a notice of termination of its dealer/supplier agreement, declining to extend the term of the agreement. This letter does not state the effective date of the termination of the agreement.
- 26. In letters dated September 28, 2016, EFT Holdings notified EPA, Respondent, and a producer of the pesticides that Respondent's Supplemental Distributor Agreements for Decon Seven Part 1 and Decon Seven Part 2 were terminated effective immediately.
- On October 3, 2016, EPA received EFT Holdings' notice regarding Decon Seven Part 1 and Decon Seven Part 2.
- 28. Decon Seven Part 1, Decon Seven Part 2, D7 Part 1 and D7 Part 2 are each a pesticide as defined under section 2(u) of FIFRA, 7 U.S.C. § 136(u).
- Decon Seven Part 1 and Decon Seven Part 2 are not currently registered under Section 3 of FIFRA, 7 U.S.C. § 136a.
- 30. In informing Respondent that EPA had registered the New D7 Products, EPA stated the following:

"Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance."

- To produce its products, Respondent uses manufacturers such as Royal Chemical Company.
- 32. To distribute and sell its products, Respondent uses its own website "www.Decon7.com" and the websites of its agents and distributors, including "www.allsafeindustries.com" and a website operated by JBI Distributors, LLC at "www.jbidistributors.com."

III. BASIS FOR ORDER

 In early 2017, EPA Region 9 received information regarding potential FIFRA violations associated with Respondent's distribution and sale of Decon Seven Part 1 and Decon Seven Part 2.

A. 2017 Establishment Inspections

- On July 5 and 13, 2017, a federally-credentialed inspector from the Arizona Department of Agriculture conducted inspections of Respondent's facility at 8541 E. Anderson Dr. #106 Scottsdale, AZ 85225.
- 35. As part of the same investigation, on July 28, 2017, the federally-credentialed inspector from the Arizona Department of Agriculture conducted an inspection of JBI Distributors, LLC ("JBI Distributors") by conducting an interview of one of the owners at the Arizona Department of Agriculture.
- 36. On August 1, 2017, federally-credentialed inspectors from EPA Region 5 conducted an inspection of Royal Chemical Company in Macedonia, Ohio. That facility is registered with EPA as a pesticide producing establishment and assigned the EPA Establishment Number 10508-OH-1. The July 5, 13, 28 and August 1 inspections are together "the 2017 inspections").
- During the 2017 inspections, the inspectors obtained product samples and related documentation for Respondent's distribution and sale of Decon Seven Part 1 (EPA Reg.

No. 74436-1-89833), and Decon Seven Part 2 (EPA Reg. No. 74436-2-89833) (together, the "Decon7 Products"). The inspectors were also provided access to where Decon7 products were being held for distribution and sale.

38. Review of these inspection reports and accompanying documentation revealed the following observations, as referenced in Paragraphs 39 through 61, below.

Decon 7 Products Labeling

- 39. The Decon7 Products are each identified on its label as a supplemental distributor pesticide product ("distributor product") under EFT Holdings' product registration through referencing their respective registration numbers as EPA Registration Number 74436-1-89833 for Decon Seven Part 1, and 74436-2-89833 for Decon Seven Part 2.
- 40. Distributor products can delete specific claims made by the registered product but cannot have claims that are significantly different from the master labels. The master label for Decon Seven Part 1 is the one for EPA Reg. No. 74436-1 and the master label for Decon Seven Part 2 is the one for EPA Reg. No. 74436-2 (together, these are the "Decon7 Products' Master Labels").
- 41. The labels for each of the Decon7 Products includes the website "www.Decon7.com" ("Decon7 website") on the front label. The Decon7 website is labeling pursuant to FIFRA section 2(p)(2)(B), 7 U.S.C. § 136(p)(2)(B), because the Decon7 Products contain a reference to the Decon7 website.
- 42. The Decon7 website contains statements regarding:
 (A) use by the federal government, including: "Used by the FBI, Secret Service, DEA, and EPA" and "The Federal government used D7 following the 9/11 anthrax attacks to decontaminate the Hart Senate Building, U.S. Post Office in Washington D.C. and NBC studio offices in New York City."
 (B) the safety of the Decon7 Products, including: "Safety Environmentally friendly D7 includes substances found in ordinary household products. D7 is biodegradable and with a final pH of 9.8 it is gentle enough for household use."
- 43. The statements in Paragraph 42 are not on the Decon7 Products' Master Labels.
- 44. The statements about the Decon7 Products being used by various federal agencies are false and misleading statements pursuant to 40 C.F.R. § 156.10(a)(5)(v) because such statements imply that the Decon7 Products are recommended or endorsed by an agency of the Federal Government.
- 45. The statements in Paragraph 42(B) about the safety of the Decon7 Products are false and misleading statements pursuant to 40 C.F.R. § 156.10(a)(5)(ix) because saying these products are "environmentally friendly," "includes substances found in ordinary

household products," "biodegradable," and "gentle enough for household use" implies that the Decon7 Products are harmless. As noted in Paragraph 22 above, and as indicated on the Decon7 Products' Master Labels, Decon Seven Part 1 and Decon Seven Part 2 each have the signal word "Danger" as is required of a Toxicity Category Class I Pesticide. Decon Seven Part 1 causes skin burns and Decon Seven Part 2 can cause irreversible eye damage. The Decon7 Products' Master Labels identify these products as corrosive.

- 46. At the time of the 2017 inspections, the Decon7 website also contained statements regarding the effectiveness of the Decon7 Products, including:
 - (A) a statement on "The Significance of 7" stating "D7 is capable of killing up to 99.99999%" of Staphylococcus aureus, E. coli, Salmonella enterica, Pseudomonas aeruginosa, and Staphylococcus aureus MRSA; and
 - (B) a link to a log reduction chart that contains the statements that "a 3-Log Reduction on a surface with 1,000,000 microbes would leave 1,000 microbes, which equals to a 99.9% reduction in potentially harmful microorganisms" while a "7 log reduction" means that "the number of germs is 10,000,000 times smaller."
- 47. The statements and graphic representations discussed in Paragraph 46 are not on the Decon7 Products' Master Labels. The allowable claims are 99.9% kill claim for bacteria and 99.99% kill claim for viruses.
 - 48. These statements and graphic representations about the effectiveness of the Decon7 Products are false and misleading with respect to the product's effectiveness pursuant to 40 C.F.R. § 156.10(a)(5)(ii) because these statements claim a level of effectiveness beyond that which EPA allows.
 - 49. Because the Decon 7 Products have product labeling that contains false and misleading statements as described in Paragraphs 42 through 48 above, the Decon 7 Products are each considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).
 - 50. Misbranding in the ways described in Paragraphs 42 through 48, distribution and sale of the Decon7 Products is prohibited under section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

Claims Made as Part of Distribution or Sale of the Decon 7 Products

- 51. JBI Distributors is an agent of Respondent. JBI Distributors operates the website "jbidistributors.com" (the "JBI website"). Other marketing materials used by JBI Distributors at the time of the 2017 inspections include a presentation on the JBI website (the "Presentation") and a hard copy brochure that states "Many Threats, One Solution" on its first page (the "Brochure").
- 52. The JBI website, the Presentation, and the Brochure contain statements regarding federal government use, safety, and effectiveness of the Decon7 Products including:
 - A. "The powerful, proven D7 formula is used by the FBI, Secret Service, DEA and EPA" on the JBI website;
 - B. "Tested and Certified by EPA" in the Presentation;
 - C. "Used by the EPA after Hurricane Katrina to clean commercial buildings and homes" in the Presentation;
 - D. "Safety Environmentally friendly D7 includes substances found in ordinary household products" and "D7 is biodegradable" on the JBI website;
 - E. "Kills 99.9999% spores molds bacterial viruses chemicals" on the JBI website;
 - F. "Kills 99.9999%* of all Chemical & Biological weapons, bacteria, viruses, spores, molds & odors" with "*Kill rates vary. Test results available upon request" in the Brochure; and
 - G. "All forms of bio films containment and elimination" and "lice" in the Presentation.
- 53. EPA has reason to believe that the JBI website, the Presentation, and the "Many Threats" brochure are part of Respondent's distribution or sale of the Decon7 Products because JBI Distributors uses these marketing materials to generate sales of the Decon7 Products and receives a sales commission from Respondent.
- 54. Distributing or selling a registered pesticide with claims that substantially differ from claims made in connection with its registration under section 3 of FIFRA is prohibited by Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B).
- 55. The claims about the Decon7 Products in Paragraph <u>52</u> concerning federal agency use, safety, and effectiveness substantially differ from the claims made as part of the registration for the distributor products of the EFT Holdings registrations (EPA Reg. No. 74436-1 and EPA Reg. No. 74436-2), as discussed in Paragraphs <u>42</u> through <u>48.</u>
- 56. In addition, claims made on the JBI website, in the Presentation, and in the Brochure regarding the uses of the Decon7 Products substantially differ from the registered uses and claims made as part of the registration of the distributor products of the EFT Holdings registrations (EPA Reg. No. 74436-1 and EPA Reg. No. 74436-2). These distributor products are not registered for bio films, lice, chemical or biological weapons, or spores.

57. If at the time of the 2017 inspections the Decon7 Products were distributor products registered under the EFT Holdings registrations, then claims about the Decon7 Products on the Decon7 website, JBI website, in the Presentation, and in the Brochure violate Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B) because these claims are substantially different from the registered uses and claims made as part of the registration of the distributor products of the EFT Holdings registrations (EPA Reg. No. 74436-1 and EPA Reg. No. 74436-2).

Production of the Decon 7 Products

- 58. EPA has reason to believe that at the time of the 2017 inspections the Decon7 Products did not meet the requirements for supplemental distribution at 40 C.F.R. § 152.132.
- 59. In August 2017, Decon7 Products were manufactured at Royal Chemical Company in Macedonia, Ohio. That facility is registered with EPA as a pesticide producing establishment and assigned the EPA Establishment Number 10508-OH-1. Royal Chemical Company performs toll manufacturing at its five locations in Ohio, Pennsylvania, Tennessee, Texas, and California.
- On or about October 10, 2016, Respondent signed an agreement with Royal Chemical Company to produce the Decon7 Products. Royal Chemical Company began to manufacture the Decon7 Products in August, 2016.
- 61. EPA has reason to believe that Royal Chemical Company did not have permission from the registrant, EFT Holdings, to produce these supplemental products. Pursuant to 40 C.F.R. § 152.132(b), supplemental distribution requires that the distributor product is produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with §152.30) who produces, packages, and labels the registered product. As discussed in Paragraph 26, EFT Holdings gave notice to its producer in late September 2016 that it had terminated Respondent's distributor contract and Respondent signed the October 10, 2016 agreement with Royal Chemical Company shortly after EFT Holdings gave this notice.
- 62. Since the Decon7 Products did not meet the requirements for supplemental distribution at 40 C.F.R. § 152.132, the Decon7 Products are each considered an unregistered pesticide product whose distribution and sale is prohibited under section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 63. Since the Decon7 Products failed to meet the requirements for supplemental distribution at 40 C.F.R. § 152.132, the Decon7 Products are each considered a misbranded pesticide pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A) because their labels portraying these products as supplemental distributor products are false and misleading.

Distribution and sale of the misbranded Decon7 Products is prohibited under section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

B. 2018 Website Claims

- 64. On several dates in February and March, 2018, a federally-credential inspector reviewed the claims concerning D7 on the websites of "www.Decon7.com" "jbidistributors.com" and "www.allsafeindustries.com." Review of these websites revealed the following observations, as referenced in Paragraphs 65 through 74, below.
- 65. The Decon7 website (last visited February 9, 2018) offers for sale and contains statements regarding "liquid D7" that Respondent is offering for sale as kits of D7 Part 1 and Part 2. The Decon7 website links potential purchasers to the website "www.allsafeindustries.com" (the "all safe industries website") where the product is available for purchase.
- 66. The JBI, Decon7, and all safe industries websites do not state the EPA registration number of the liquid D7 product that Respondent is offering for sale as kits of D7 Part 1 and D7 Part 2.
- 67. EPA has reason to believe that these references to D7 Part 1 and Part 2 are to the Decon7 Products because Respondent had significant supplies available during the 2017 inspections and the product numbers visible on these websites correspond to the product numbers of the Decon7 Products being sold during the 2017 inspections.
- 68. The Decon7 website is labeling of the Decon7 Products, as discussed above at Paragraph 41. In addition, the all safe industries website is labeling of the Decon7 Products pursuant to FIFRA section 2(p)(2)(B), 7 U.S.C. § 136(p)(2)(B), because the Decon7 Products contain a reference to the Decon7 website, and the Decon7 website directs customers to the all safe industries website.
- 69. As discussed at Paragraphs <u>39</u> through <u>63</u> above, EPA has reason to believe that the Decon7 Products are each an unregistered and misbranded pesticide product, whose distribution and sale is prohibited under sections 12(a)(1)(A) and (E) of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A) and (E).
- 70. EPA also has considered that the liquid D7 Part 1 and Part 2 being offered for sale at the Decon7 and all safe industries websites may also be D7 Part 1 (EPA Reg. No. 89833-3) and D7 Part 2 (EPA Reg. No. 89833-4) (the "New D7 Products") because at the time of the 2017 inspections, Respondent planned to begin selling the D7 products under its own registration in the near future.
- 71. The Decon7 website (last visited February 9, 2018) and the all safe industries website (last visited February 28, 2018) both contain statements about liquid D7 offered for sale

- as kits of D7 Part 1 and D7 Part 2 that include "...used by the FBI, Secret Service, DEA, and EPA."
- 72. The Decon7 website (last visited February 9, 2018) also contains statements about liquid D7 offered for sale as kits of D7 Part 1 and D7 Part 2 that include "Safety Environmentally friendly D7 includes substances found in ordinary household products. D7 is biodegradable and with a final pH of 9.8 it is gentle enough for household use."
- 73. The statements in Paragraphs 71 and 72 are not on the New D7 Products' Master Labels.
- 74. The Decon7 website (last visited February 9, 2018) contains statements about liquid D7 offered for sale as kits of D7 Part 1 and D7 Part 2 that include claims regarding uses of D7 including that it "eradicates ... viruses, molds, spores ... Escherichia coli 0157:H7 (ATCC 35150) ... Staphylococcus aureus MRSA (Methicillin resistant) (ATCC 33592)" and is "fungicidal against Aspergillus niger (ATCC 16404), Penicillium digitatum (ATCC 90595)."
- 75. These statements are not on the New D7 Products' Master Labels. The New D7 Products are not registered for use against viruses, molds, spores, Staphylococcus aureus MRSA (Methicillin resistant), or as a fungicidal against Aspergillus niger (ATCC 16404), or Penicillium digitatum (ATCC 90595).
- 76. EPA has reason to believe that the claims discussed in Paragraphs <u>71</u>, <u>72</u> and <u>74</u> are claims being made as part of the distribution and sale of the New D7 Products. EPA considers the claims discussed in Paragraphs <u>71</u>, <u>72</u> and <u>74</u> to be substantially different from the claims made as part of the registration for the New D7 Products.
- 77. Distributing and selling the New D7 Products with the claims discussed in Paragraphs 71, 72 and 74 is a violation of Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B) because these claims substantially differ from the registered uses and claims made as part of the registration of the New D7 Products.

Summary of Basis for the Order

- 78. Because EPA has determined that the Decon7 Products are pesticides that are not registered under Section 3 of FIFRA, 7 U.S.C. § 136a, and Respondent has distributed and sold the Decon7 Products, EPA has reason to believe that Respondent distributed or sold unregistered pesticides, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 79. Because EPA has determined that the Decon7 Products has labeling that contains statements that have not been approved by the Administrator and that are false and misleading, and Respondent has distributed and sold the Decon7 Products, EPA has reason to believe that Respondent distributed or sold misbranded pesticides, as that term

- is defined by section 2(q) of FIFRA, 7 U.S.C. § 136(q), in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).
- 80. Because EPA has determined that the Decon7 website and all safe industries websites continue to contain statements that have not been approved by the Administrator, and to have claims that substantially differ from the registered uses and claims made as part of the registration of the New D7 Products, and EPA has reason to believe that Respondent is distributing or selling the New D7 Products with these claims, EPA has reason to believe that Respondent distributed or sold registered pesticides with claims that substantially differed from the uses and claims approved by EPA, in violation of Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B).

III. ORDER

- Pursuant to the authority in section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Decon7 Systems LLC to **immediately stop** the sale, use or removal of Decon Seven Part 1 (EPA Reg. No. 74436-1-89833), and Decon Seven Part 2 (EPA Reg. No. 74436-2-89833)² (together, the "Decon7 Products") under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
 - 82. This Order shall extend to all quantities and sizes of the Decon7 Products intended for sale or distribution, including:
 - A. Any Decon7 Products marketed under alternate brand names; and
 - Any Decon7 Products returned to Decon7 from its distributors, customers, or other end-users.
- 83. The products described in Paragraph <u>81</u> shall not be used, sold, offered for sale, held for sale, shipped, delivered for shipment, received, or having so received, shall not be delivered, offered for delivery, moved or removed for disposal from any facility or establishment for any reason, unless approved by EPA in writing. Any proposal for movement of the products so described shall be submitted to Scott McWhorter, Water and Pesticides Branch, Enforcement Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, California 94105, and shall include:
 - A. The purpose for which the movement is being requested;

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² Since the EPA has evidence showing these products are not currently registered as supplemental distributor pesticide products, the referenced numbers are used solely for product identification purposes and such use in this Order does not reflect an EPA belief that this product is properly registered.

- An accounting of the quantities of the product to be moved, including location(s), quantities from each location, and container size for the products to be moved; and
- C. The destination location to which the product will be moved.
- 84. Within 48 hours of receipt of this Order, Respondent and Respondent's agents will:
 - (a) remove any false and misleading statements from any website under its control for the pesticide products Decon7 D7 Part 1 (EPA Reg. No. 89833-3) and D7 Part 2 (EPA Reg. No. 89833-4) (the "New D7 Products") and
 - (b) cease distributing or making available hard-copy advertising material with false and misleading statements for the Decon7 Products or the New D7 Products, such as the Brochure and Presentation identified above, in Paragraph <u>51</u>.
- 85. Within 10 days of receipt of this Order, Decon7 shall submit to EPA an accounting of all products described in Paragraph 81. The report shall be submitted to Scott McWhorter, Water and Pesticides Branch, Enforcement Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, California 94105, and shall include:
 - A. A description of all existing product inventory, including the location(s) where the products are held, quantities, and container size. This information must be updated on a weekly basis for four weeks, on a monthly basis for the following six months, and thereafter only upon further change to the information;
 - A complete list of Decon7's distributors and direct-sale customers and records of all sales and distributions made to such entities since January 1, 2016; and
 - C. Provisions to maintain records of the distribution (e.g., reformulation, repackaging, relabeling, disposal) of products and to make the records available to EPA upon request. Such records must include information on the method, the quantity, and the location of the disposition and/or disposal.
 - D. You may, if you desire, assert a business confidentiality claim for all or part of the information submitted in accordance with 40 C.F.R. Part 2. The information qualifying as business confidential material will be disclosed by EPA only to the extent and by the procedures set forth in 40 C.F.R. Part 2 Subpart B. Unless you make a claim at the time you submit the information, it may be made available to the public by EPA without further notice to you. If you do assert a business confidentiality claim, you must follow the procedures set forth in the attached Exhibit A.

- Any agent, owner, or operator of Decon7 violating the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in section 14 of FIFRA, 7 U.S.C. § 1361.
- 87. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- This Order shall be effective immediately upon receipt by Decon7, or any agents of Decon7.
- This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 90. If any provision or provisions of this Order is/are subsequently held to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

V. OTHER MATTERS

- Respondent may seek federal judicial review of this Order pursuant to Section 16 of FIFRA, 7 U.S.C. § 136n.
- For additional information about this Order, please contact Scott McWhorter, Enforcement Case Officer, at 415-972-3584, or Margaret Alkon, Attorney, at 415-972-3890.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, COMPLAINANT

DATE: 3 14 2018

Elizabeth Berg

Acting Assistant Director,

Water & Pesticides Branch

Enforcement Division

U.S. Environmental Protection Agency, Region IX

EXHIBIT A

If you wish to assert a claim of business confidentiality, you must clearly mark each page of each document included in your claim with a legend such as "trade secret", "proprietary", or "company confidential." If you claim information submitted as confidential, you must also provide a redacted version of the information with all confidential business information deleted. For any information and documents in which you assert a claim of business confidentiality, please answer the following questions:

- What specific portions of the information are alleged to be entitled to confidential treatment? Specify by page, paragraph, and sentence when identifying the information subject to your claim.
- 2. For what period of time do you request that the information be maintained as confidential (e.g., until a certain date, until the occurrence of a specified event or permanently)? If the occurrence of a specific event will eliminate the need for confidentiality, specify that event. Additionally, explain why the information should be protected for the time period you have specified.
- 3. What measures have you taken to protect the information claimed as confidential from undesired disclosure? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
- 4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
- 5. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
- 6. For each category of information claimed as confidential, explain with specificity whether disclosure of the information is likely to result in substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effect. How could your competitors make use of this information to your detriment?
- 7. Is there any other explanation you deem relevant to the EPA's determination of your business confidentiality claim that is not covered in the preceding requests? If so, you may provide such additional explanation.

You must furnish comments to the above requests concurrent with your response, if you have claimed any information as business confidential. See 40 C.F.R. § 2.204(e)(2). Pursuant to 40 C.F.R. § 2.205(b)(2), you may request an extension of this deadline. The EPA will construe your failure to furnish timely comments as a waiver of your confidentiality claim, consistent with 40 C.F.R. § 2.204(e)(1).



U.S. EPA Small Business Resources Information Sheet

The United States Environmental Protection Agency provides an array of resources to help small businesses understand and comply with federal and state environmental laws. In addition to helping small businesses understand their environmental obligations and improve compliance, these resources will also help such businesses find cost-effective ways to comply through pollution prevention techniques and innovative technologies.

Office of Small and Disadvantaged Business Utilization (OSDBU)

www.epa.gov/aboutepa/about-officesmall-and-disadvantaged-businessutilization-osdbu

EPA's OSBBU advocates and advances business, regulatory, and environmental compliance concerns of small and socio-economically disadvantaged businesses.

EPA's Asbestos Small Business Ombudsman (ASBO)

www.cpa.gov/resources-smallbusinesses/asbestos-small-businessombudsman or 1-800-368-5888

The EPA ASBO serves as a conduit for small businesses to access EPA and facilitates communications between the small business community and the Agency.

Small Business Environmental Assistance Program

https://nationalsbeap.org

This program provides a "one-stop shop" for small businesses and assistance providers seeking information on a wide range of environmental topics and statespecific environmental compliance assistance resources.

EPA's Compliance Assistance Homepage

www.epa.gov/compliance

This page is a gateway to industry and statute-specific environmental resources, from extensive web-based information to hotlines and compliance assistance specialists.

Compliance Assistance Centers

www.complianceassistance.net

EPA sponsored Compliance Assistance Centers provide information targeted to industries with many small businesses. They were developed in partnership with industry, universities and other federal and state agencies.

Agriculture

www.epa.gov/agriculture

Automotive Recycling

www.ecarcenter.org

Automotive Service and Repair www.ccar-greenlink.org or 1-888-GRN-LINK

Chemical Manufacturing

www.chemalliance.org

Construction

www.cicacenter.org

Education

www.campuserc.org

Food Processing

www.fpeac.org

Healthcare

www.hercenter.org

Local Government

www.lgean.org

Surface Finishing

http://www.sterc.org

Paints and Coatings

www.paintcenter.org

Printing

www.pneac.org

Ports

www.portcompliance.org

Transportation

www.tercenter.org

U.S. Border Compliance and Import/Export Issues

www.bordercenter.org

EPA Hotlines and Clearinghouses

www.epa.gov/home/epa-hotlines

EPA sponsors many free hotlines and clearinghouses that provide convenient assistance regarding environmental requirements. Examples include:

Clean Air Technology Center (CATC) Info-line

www.epa.gov/cate or 1-919-541-0800

Superfund, TRI, EPCRA, RMP, and Oil Information Center

1-800-424-9346

EPA Imported Vehicles and Engines Public Helpline

www.epa.gov/otaq/imports or 1-734-214-4100

National Pesticide Information Center www.npic.orst.edu or 1-800-858-7378

National Response Center Hotline to report oil and hazardous substance spills - http://nrc.uscg.mil or 1-800-424-8802

Pollution Prevention Information Clearinghouse (PPIC) -

www.epa.gov/p2/pollution-preventionresources#ppic or 1-202-566-0799

Safe Drinking Water Hotline -

www.epa.gov/ground-water-and-drinkingwater/safe-drinking-water-hotline or 1-800-426-4791

Toxic Substances Control Act (TSCA)

tsca-hotline@epa.gov or 1-202-554-1404

U.S. Small Business Resources

Small Entity Compliance Guides

https://www.epa.gov/reg-flex/small-entity-compliance-guides

EPA publishes a Small Entity Compliance Guide (SECG) for every rule for which the Agency has prepared a final regulatory flexibility analysis, in accordance with Section 604 of the Regulatory Flexibility Act (RFA).

Regional Small Business Liaisons

www.epa.gov/resources-small-busmesses/epa-regional-office-small-business-liaisons

The U.S. Environmental Protection Agency (EPA) Regional Small Business Liaison (RSBL) is the primary regional contact and often the expert on small business assistance, advocacy, and outreach. The RSBL is the regional voice for the EPA Asbestos and Small Business Ombudsman (ASBO).

State Resource Locators

www.envcap.org/statetools

The Locators provide state-specific contacts, regulations and resources covering the major environmental laws.

State Small Business Environmental Assistance Programs (SBEAPs)

https://nationalsbeap.org/states/list

State SBEAPs help small businesses and assistance providers understand environmental requirements and sustainable business practices through workshops, trainings and site visits.

EPA's Tribal Portal

www.epa.gov/tribalportal

The Portal helps users locate tribal-related information within EPA and other federal agencies.

EPA Compliance Incentives

EPA provides incentives for environmental compliance. By participating in compliance assistance programs or voluntarily disclosing and promptly correcting violations before an enforcement action has been initiated, businesses may be eligible for penalty waivers or reductions. EPA has two such policies that may apply to small businesses:

EPA's Small Business Compliance Policy

www.epa.gov/enforcement/small-businesses-andenforcement

EPA's Audit Policy

www.epa.gov/compliance/epas-audit-policy

Commenting on Federal Enforcement Actions and Compliance Activities

The Small Business Regulatory Enforcement Fairness Act (SBREFA) established a SBREFA Ombudsman and 10 Regional Fairness Boards to receive comments from small businesses about federal agency enforcement actions. If you believe that you fall within the Small Business Administration's definition of a small business (based on your North American Industry Classification System designation, number of employees or annual receipts, as defined at 13 C.F.R. 121.201; in most cases, this means a business with 500 or fewer employees), and wish to comment on federal enforcement and compliance activities, call the SBREFA Ombudsman's toll-free number at 1-888-REG-FAIR (1-888-734-3247).

Every small business that is the subject of an enforcement or compliance action is entitled to comment on the Agency's actions without fear of retaliation. EPA employees are prohibited from using enforcement or any other means of retaliation against any member of the regulated community in response to comments made under SBREFA.

Your Duty to Comply

If you receive compliance assistance or submit a comment to the SBREFA Ombudsman or Regional Fairness Boards, you still have the duty to comply with the law, including providing timely responses to EPA information requests, administrative or civil complaints, other enforcement actions or communications. The assistance information and comment processes do not give you any new rights or defenses in any enforcement action. These processes also do not affect EPA's obligation to protect public health or the environment under any of the environmental statutes it enforces, including the right to take emergency remedial or emergency response actions when appropriate. Those decisions will be based on the facts in each situation. The SBREFA Ombudsman and Fairness Boards do not participate in resolving EPA's enforcement actions. Also, remember that to preserve your rights, you need to comply with all rules governing the enforcement process.

EPA is disseminating this information to you without making a determination that your business or organization is a small business as defined by Section 222 of the Small Business Regulatory Enforcement Fairness Act or related provisions.